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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/24/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent@foleyhoag.com

Office Action Summary	Application No.	Applicant(s)	
	09/166,701	ODIDI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-9,11,12,23,28-31 and 33-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-9,11,12,23,28-31 and 33-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Withdrawal of Finality

1. In view of the Appeal Brief filed on 6/10/08, PROSECUTION IS HEREBY REOPENED. The reasons set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618.

Response to Amendment

Status of Claims

2. Claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36 are pending in this office action.

3. The rejections of claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36 under 35 U.S.C. 103(a) as being unpatentable over Weiss (US 4,252,786) in view of Jenkins (US 4,940,587) is withdrawn because the affidavit under 37 CFR 1.132 filed 5/13/09 is sufficient to overcome the rejection of claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36.

4. The rejections of claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 - 28** of U.S. Patent No. **7090867** is withdrawn due to the filing and approval of a terminal disclaimer.

5. The rejection of claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1- 22** of U.S. Patent Application No. **11/473,386** is withdrawn due to the filing and approval of a terminal disclaimer.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7-9, 11-12, 23, 28-31 and 33-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claim 1 recites limitations:

"…about 1-50% by weight polymers of acrylic acid….".

"…about 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose",

"between 0-10% by weight talc" and

"between 0-10% by weight magnesium stearate" and

"…..wherein said acrylic acid crosslinked polymers, hydroxyethylcellulose and hydroxypropyl methyl cellulose, talc, magnesium stearate"…are provided as a homogenous mixture.

Specifically, pages 3- 4 of the specification discloses hydroxyethyl cellulose as 1-60% and hydroxypropyl cellulose as 1-75%, there is no recitation of "1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose" (see lines 225-32 and 1-5 respectively). Also there is no recitation of "between 0-10% by weight of talc and between 0-10% by weight magnesium stearate". Page 4 of the specification recites "about less than 10% by weight of talc and about less than 10% by weight magnesium stearate". The recitation of "less than about 10%" does not provide support that the talc (or magnesium stearate) may not be present at all, such as encompasssing 0% as now

claimed. The recitation of about less than 10% and that all examples contained talc and/or magnesium stearate clearly described that the components were present.

Page 3 also recites “blending about 1 to 80% pharmaceutically active agent with about 1 to 70% by weight uncrosslinked, water soluble polymers to form a homogeneous blend; - granulating said homogeneous blend with a granulating solution to form a wet mass of granules and kneading said wet mass”. There is no recitation that the homogenous bled comprises crosslinked polymers, hydroxyethylcellulose and hydroxypropyl methyl cellulose, talc, magnesium stearate as recited in instant claim 1. Page 5 of the specification also states specifically that the homogenous mixture is only with blending 1-80% of a selected pharmaceutically active agents with about 1-60% of uncrosslinked linear.....to form a homogenous mixture (see lines 1-8). Also, page 8, lines 23-30 also indicate that the talc, magnesium stearate, etc. where not envisioned at the time of filing to be part of a homogeneous mixture but are added to "milled granules" of -80% of a selected pharmaceutically active agents with about 1-60% of uncrosslinked linear.....to form a homogenous mixture.

Claim 4 recites “are carboxyvinyl polymer resins”. Page 4 lines 27-28 recites "crosslinked polymer suitable for use ….are polymers of acrylic acid crosslinked with polyalkenyl alcohols or divinyl glycol but no recitation of “are carboxyvinyl polymer resins” as claimed.

Claim 8 recites the composition additionally comprises between 0-95% weight of granulating tablet. Page 3 of the specification recites about less than 95% by weight of granulating and tableting aids.

Claim 9 recites limitations:

"…about 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose",

"between 0-10% by weight talc" and

"between 0-10% by weight magnesium stearate"

"between 0-95% by weight granulating and tabletting aids,

"…..wherein said acrylic acid crosslinked polymers, hydroxyethylcellulose and hydroxypropyl methyl cellulose, talc, magnesium stearate" are provided as a homogenous mixture (see explanation pertaining to claim 1). Additionally page 3 of the specification recites "about less than 95% by weight of granulating and tablet aids" which is not the same as between 0 and 95%.

Claim 23 recites:

"…about 1-50% by weight polymers of acrylic acid….".

"…about 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose", see explanation given above for claim 1.

Claim 30 recites:

"…about 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose",

"…about 1-50% by weight of at least one carboxyvinyl polymer resin"

"between 0-10% by weight talc" and

"between 0-10% by weight magnesium stearate"

"between 0-95% by weight granulating and tabletting aids,

"…..wherein said acrylic acid crosslinked polymers, hydroxyethylcellulose and hydroxypropyl methyl cellulose, talc, magnesium stearate" are provided as a homogenous mixture".

Claim 33 recites

"…about 1-50% by weight of polymers of acrylic acid crossed linked with polyvinyl alcohols or divinyl alcohol; "…about 1-58% by weight of a mixture of hydroxyethyl cellulose and hydroxypropyl methylcellulose wherein said acrylic acid crosslinked polymers, hydroxyethylcellulose and hydroxypropyl methyl cellulose, talc, magnesium stearate" are provided as a homogenous mixture".

Claim 34 recites:

"1-25% of hydroxyethyl cellulose",

Claim 35 recites:

"1-35% hydroxypropyl methylcellulose" and

Claim 36 recites:

1-25% of hydroxyethyl cellulose and 1-35% hydroxypropyl methylcellulose"

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. In other words, a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species. The various ranges set forth in the claims are not found in the specification.

Applicant is invited to indicate by page and line number where such limitations are described.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
6/14/10

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618